

Spirovac

Authorised

- *Leptospira borgpetersenii*, serovar Hardjo-bovis, Inactivated

Product identification

Medicine name:

Spirovac

Active substance:

Leptospira borgpetersenii, serovar Hardjo-bovis, Inactivated

Target species:

Cattle

Route of administration:

Subcutaneous use

Product details

Active substance and strength:

Leptospira borgpetersenii, serovar Hardjo-bovis, Inactivated
2.00 relative potency / 2.00 millilitre(s)

Pharmaceutical form:

Suspension for injection

Withdrawal period by route of administration:

Subcutaneous use:

-

Cattle

- Meat and offal. 0 day
- Milk. 0 day

Anatomical therapeutic chemical veterinary (ATCvet) codes:

QI02AB03

Legal status of supply:

Veterinary medicinal product subject to veterinary prescription

Authorisation status:

Valid

Authorised in:

Portugal

Package description:

Container: 5 doses (10ml) Glass type I vials.Closure: Chlorobutyl stopper with aluminium overseal.Outer Packaging: Cardboard carton with package insert leaflet.Pack sizes: 5 doses (10 ml).

Container: 25 doses (50ml) Glass type I vials.Closure: Chlorobutyl stopper with aluminium overseal.Outer Packaging: Cardboard carton with package insert leaflet.Pack sizes: 25 doses (50ml).

Additional information

Entitlement type:

Marketing Authorisation

Legal basis of product authorisation:

Full application (Article 12(3) of Directive No 2001/82/EC)

Marketing authorisation holder:

Zoetis Portugal Lda.

Marketing authorisation date:

23/05/2016

Manufacturing sites for batch release:

Zoetis Belgium

Responsible authority:

Directorate General For Food And Veterinary

Authorisation number:

925/01/16RIVPT

Date of authorisation status change:

23/05/2016

Reference member state:

Ireland

Procedure number:

IE/V/0420/001

Concerned member states:

Germany Portugal United Kingdom (Northern Ireland)

To consult adverse reactions on veterinary medicinal products please go to www.adrreports.eu/vet

Documents

Summary of Product Characteristics

Combined File of all Documents